Insert logo of [authorising body](https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#terms-used-in-the-guideline)

|  |
| --- |
| This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. |

**PATIENT GROUP DIRECTION (PGD)**

**Supply of a progestogen only contraceptive pill (POP) in location/service/organisation**

Version Number 2.1

|  |
| --- |
| **Change History** |
| **Version and Date** | **Change details** |
| Version 1April 2020 | New template |
| Version 1.1November 2020 | Minor rewording and highlighting of contents cautions section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.Porphyria added as exclusion criteria.  |
| Version 2.0April 2023 | Updated template – amended references and minor editing and wording changes/clarifications.  |
| Version 2.1April 2024 | Revised content with drospirenone information now UK product is available. Expanded on other POP active ingredients to distinguish. Added note re low risk of breast cancer. Updated references. Updated SLWG. |

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations’ PGD governance system. The organisation’s governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

**PGD DEVELOPMENT GROUP**

|  |  |
| --- | --- |
| Date PGD template comes into effect:  | April 2023 |
| Review date | September 2025 |
| Expiry date:  | March 2026 |

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2022.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Dr Cindy Farmer | Vice President, Professional Learning and Development Faculty of Sexual and Reproductive Healthcare (FSRH)  |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)  |
| Vicky Garner | Consultant Midwife British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | Clinical Nurse Specialist  |
| Kate Devonport | National Unplanned Pregnancy Advisory Service (NUPAS)  |
| Chetna Parmar | Pharmacist adviser Umbrella  |
| Heather Randle | Royal College of Nursing (RCN) |
| Carmel Lloyd | Royal College of Midwives (RCM) |
| Clare Livingstone | Royal College of Midwives (RCM) |
| Kirsty Armstrong  | National Pharmacy Integration Lead, NHS England |
| Dipti Patel | Local authority pharmacist  |
| Emma Anderson | Centre for Pharmacy Postgraduate Education (CPPE) |
| Alison Crompton | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist  |
| Bola Sotubo | NHS North East London ICB pharmacist |
| Sim Sesane  | CASH Nurse Consultant, MSI Reproductive Choices |
| Portia Jackson | Lead Pharmacist iCaSH, Cambridgeshire Community Services |
| Tracy Rogers | Director, Medicines Use and Safety, Specialist Pharmacy Service  |
| Sandra Wolper  | Associate Director Specialist Pharmacy Service |
| Jo Jenkins  | Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service |
| Rosie Furner (Working Group Co-ordinator)  | Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service |

**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

**ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS**

**This page may be deleted if replaced with a format agreed according to local PGD policy with relevant approvals and authorisation.**

The PGD is not legally valid until it has had the relevant organisational authorisations.

To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation. You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and [NICE MPG2 PGD 2017](https://www.nice.org.uk/Guidance/MPG2).

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  | **Job title and organisation**  | **Signature** | **Date** |
| **Senior doctor**  |  |  |  |
| **Senior pharmacist** |  |  |  |
| **Senior representative of professional group using the PGD**  |  |  |  |
| **Person signing on behalf of** [**authorising body**](https://www.legislation.gov.uk/uksi/2012/1916/schedule/16) |  |  |  |

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

To meet legal requirements, authorising organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy and how the service is managed but this should be a signature list or an individual agreement.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

**ORGANISATIONS MAY ALSO ADD:**

* Local training and competency assessment documentation
* Other supporting local guidance or information
* Links to local PGD Policy and other supporting guidance
* Audit requirements

Any reference to a Trust protocol (either clinical to be followed as part of the administration of a medication with the PGD or for any other purpose) must be referenced and hyperlinked to ensure the practitioner acting under the PGD has direct access to the protocol for reference.

**Characteristics of staff**

|  |  |
| --- | --- |
| **Qualifications and professional registration** | Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.  |
| **Initial training** | The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy. Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. The individual must have undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - [eLfH PGD elearning programme](https://www.e-lfh.org.uk/programmes/patient-group-directions/) The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults, or level 2 safeguarding for adults and children, or equivalent |
| **Competency assessment** | * Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for contraception supply.
* Staff operating under this PGD are encouraged to review their competency using the [NICE Competency Framework for health professionals using patient group directions](https://www.nice.org.uk/guidance/mpg2/resources)
 |
| **Ongoing training and competency** | * Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided.
* Organisational PGD and/or medication training as required by employing Trust/organisation.
 |
| The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.  |

**Clinical condition or situation to which this PGD applies**

|  |  |
| --- | --- |
| **Clinical condition or situation to which this PGD applies** |  Contraception |
| **Criteria for inclusion** | * Norethisterone, levonorgestrel and desogestrel - Individual (age from menarche to 55 years) presenting for contraception.
* Drospirenone only - age from menarche to 49 years
* Consent given.
 |
| **Criteria for exclusion** | * Consent not given.
* Drospirenone only – 50 years or older
* Individuals under 16 years of age and assessed as not competent using Fraser Guidelines.
* Individuals 16 years of age and over and assessed as lacking capacity to consent.
* Established pregnancy. Note - risk of pregnancy with a negative pregnancy test is not an exclusion
* Known hypersensitivity to the active ingredient or to any constituent of the product - see [Summary of Product Characteristics](https://www.medicines.org.uk/emc)
* Acute porphyria

**Cardiovascular Disease*** Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic first attack, only if taking the method when the event occurred.

**Cancers** * Current or past history of breast cancer.
* Malignant liver tumour (hepatocellular carcinoma).

**Gastro-intestinal conditions*** Severe decompensated cirrhosis.
* Benign liver tumour (hepatocellular adenoma).
* Any bariatric or other surgery resulting in malabsorption.

**Drospirenone only*** Individuals with known hyperkalaemia or hypoaldosteronism (eg, Addison’s disease).
* Individuals currently taking potassium-sparing diuretics, aldosterone antagonists or potassium supplements (including OTC).
* Known or suspected severe hepatic disease with deranged liver function values.
* Known renal impairment (all stages) or acute renal failure.
* Known or suspected sex-steroid sensitive malignancies.

**Medicines*** Individuals using enzyme-inducing medicines/herbal products or within 4 weeks of stopping them.
* Individuals taking any interacting medicines (other than enzyme inducers), including medicines purchased – see current British National Formulary (BNF) [www.bnf.org](http://www.bnf.org) or individual product SPC <http://www.medicines.org.uk>
 |
| **Cautions including any relevant action to be taken** | * If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
* If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.
* Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
* Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn’s disease. Although the use of POP is not contra-indicated it may be less effective and so these individuals should be advised offered Long Acting Reversible Contraception (LARC).
* Individuals should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of POP.
* **Offer LARC to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.**
* **If an individual is known to be taking a medication which is known to be harmful to pregnancy a highly effective form of contraception is recommended. Highly effective methods include the LARC methods: copper IUD, LNG-IUD and implant. If a LARC method is unacceptable/unsuitable and a POP is chosen then an additional barrier method of contraception is advised.**

**See** [**FSRH advice**](https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-contraception-for-women-using-known/)**.** |
| **Action to be taken if the individual is excluded or declines treatment**  | * Explain the reasons for exclusion to the individual and document in the consultation record.
* Record reason for declining treatment in the consultation record.
* Where appropriate refer the individual to a suitable health service provider and/or provide them with information about further options.
 |

**Description of treatment**

|  |  |
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| **Name, strength & formulation of drug** | * Desogestrel 75micrograms tablets
* Levonorgestrel 30micrograms tablets
* Norethisterone 350micrograms tablets
* Drospirenone 4mg tablets (NB: pack contains active and placebo pills)

Note:* The above names the generic component of available progestogen only contraceptive pills.
* This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.
* Some desogestrel products contain excipients containing soya/nut – awareness of allergy may be required depending on product offered.
* See <http://www.mhra.gov.uk/spc-pil/> or <http://www.medicines.org.uk> for further information and further brand information including full details of adverse effects and interactions
 |
| **Legal category** | POM |
| **Route of administration** | Oral |
| **Off label use** | Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).This PGD includes inclusion criteria, exclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance. Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence. |
| **Dose and frequency of administration** | * Single tablet taken at the same time each day starting on day 1-5 of the menstrual cycle (must be day 1 for drospirenone) with no need for additional protection.
* The POP can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions are then required for 48 hours, (7 days for drospirenone), after starting and advise to have follow up pregnancy test at 21 days. (See below for drospirenone.)
* When starting or restarting the POP as quick start after levonorgestrel emergency contraception, additional contraception is required for 48 hours, (7 days for drospirenone).
* In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.
* For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines

**Drospirenone*** **Drospirenone** is started on day 1 after abortion or by day 21 after childbirth. If started at any other time, additional contraceptive precautions are required for **7** days with advice to take a follow-up pregnancy test if appropriate.
* Drospirenone is taken in a continuous cycle of 24 consecutive daily 4mg pills followed by four inactive pills (a 4-day hormone-free interval)
* FSRH recommendations on starting and switching to or from **drospirenone**, and missed pill rules/requirement for emergency contraception differ between drospirenone and other POPs. [FSRH CEU Statement: Drospirenone Progestogen-only Pill (DRSP POP) (Jan 2024) | FSRH](https://www.fsrh.org/Public/Documents/fsrh-ceu-statement-drospirenone-progestogen-only-pill-drsp-pop.aspx?WebsiteKey=f858b086-d221-4a83-9688-824162920b1b)
 |
| **Duration of treatment** | For as long as the individual requires POP and has no contraindications to the use of POP. |
| **Quantity to be supplied**  | Supply up to twelve months in appropriately labelled original packs.  |
| **Storage** | Medicines must be stored securely according to national guidelines. |
| **Drug interactions** | All concurrent medications, including those purchased should be considered for interactions.A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF [www.bnf.org](http://www.bnf.org) and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) | FSRH](https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-drug-interactions-with-hormonal.aspx)**Drospirenone**Avoid potassium sparing agents and aldosterone antagonists, or potassium supplements (including OTC) due to risk of hyperkalaemia with concomitant use of **drospirenone**:Individuals using a multivitamin/dietary supplement containing potassium may wish to consider changing to a non potassium containing product if clinically appropriate.Avoid grapefruit or grapefruit juice while taking **drospirenone**. |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) and BNF [www.bnf.org](http://www.bnf.org) The following possible adverse effects are commonly reported with POP (but may not reflect all reported adverse effects):* + Acne
	+ Breast tenderness
	+ Headache
	+ Disturbance of bleeding patterns
	+ Changes in mood/libido
	+ Weight change

**Drospirenone*** + Hyperkalaemia
 |
| **Management of and reporting procedure for adverse reactions** | * Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk>
* Record all adverse drug reactions (ADRs) in the individual’s clinical record.
* Report via organisation incident policy.
 |
| **Written information and further advice to be given to individual**  | * Provide manufacturer’s information leaflet (PIL) provided within the original pack.
* Individuals should be informed about the superior effectiveness of LARC.
* Explain mode of action, side effects, and benefits of the medicine.
* Advise on action if the individual vomits within two hours (three to four hours for **drospirenone**) of taking the pill or in cases of prolonged vomiting or severe diarrhoea. See [FSRH guidance](https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-clinical-guideline-progestogen-only-pills-aug22-amended-11july-2023-.pdf).
* Advise on missed pills (missed pills; twelve hours after normal administration time for desogestrel; twenty-four hours for **drospirenone**;three hours after normal administration time for norethisterone and levonorgestrel POPs). See [FSRH guidance](https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-clinical-guideline-progestogen-only-pills-aug22-amended-11july-2023-.pdf).
* Avoid grapefruit or grapefruit juice while taking **drospirenone**. **(Drospirenone only.)**
* Advise on risks of the medication including failure rates, serious side effects and the actions to be taken.
* Advise that risk of any pregnancy is low during use of effective contraception. Of pregnancies that occur during use of the traditional POP, 1 in 10 may be ectopic.
* Individuals should be advised that current use of progestogen-only contraceptives is associated with a small increased risk of breast cancer which reduces with time after stopping.
* A follow up review should be undertaken annually.
* Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)
* Ensure the individual has the contact details of local sexual health services.
* Advise the individual to seek advice from a pharmacist, doctor or other prescriber before starting any new medications, including those purchased.
 |
| **Advice / follow up treatment** | * The individual should be advised to seek medical advice in the event of an adverse reaction.
* The individual should seek further advice if they have any concerns.
* Review annually.
 |
| **Records** | **Record:** * The consent of the individual and/or
	+ If individual is under 16 years of age document capacity using Fraser guidelines.
	+ If individual is under 13 years of age and not competent, record action taken
	+ If individual is under 16 years and not competent, record action taken
	+ If individual over 16 years of age and not competent, record action taken
* Name of individual, address, date of birth
* GP contact details where available/appropriate
* Relevant past and present medical history
* Relevant medication history (to include over the counter, herbal medications, supplements and recreational drug use).
* Examination or microbiology finding/s where relevant.
* Any known allergies
* Name of registered health professional
* Name of medication supplied
* Date of supply
* Dose supplied
* Quantity supplied
* Advice given, including advice given if excluded or declines treatment
* Details of any adverse drug reactions and actions taken
* Advice given about the medication including, dosing regimen, side effects, benefits, and when and what to do if any concerns
* Any referral arrangements made
* Any supply outside the terms of the product marketing authorisation
* Recorded that supplied via Patient Group Direction (PGD)

Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous.* + A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
 |

**Key references**

|  |  |
| --- | --- |
| **Key references (accessed January 2024)** | * Electronic Medicines Compendium <http://www.medicines.org.uk/>
* Electronic BNF <https://bnf.nice.org.uk/>
* NICE Medicines practice guideline “Patient Group Directions” <https://www.nice.org.uk/guidance/mpg2>
* Faculty of Sexual and Reproductive Health Clinical Guideline: Progestogen-only Pills August 2022[fsrh-ceu-clinical-guideline-progestogen-only-pills-aug22-amended-11july-2023-.pdf](https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-clinical-guideline-progestogen-only-pills-aug22-amended-11july-2023-.pdf)
* FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) - Faculty of Sexual and Reproductive Healthcare](https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/)
* Faculty of Sexual and Reproductive Healthcare (2019, amended November 2020) Combined Hormonal Contraception [FSRH Clinical Guideline: Combined Hormonal Contraception (January 2019, amended October 2023) | FSRH](https://www.fsrh.org/Public/Documents/fsrh-guideline-combined-hormonal-contraception.aspx)
* Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. [UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) | FSRH](https://www.fsrh.org/Public/Public/Standards-and-Guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec.aspx?hkey=82727ce6-756b-4b88-a5ab-acaf27c48669)
* Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017)

[FSRH Clinical Guideline: Quick Starting Contraception (April 2017) | FSRH](https://www.fsrh.org/Public/Documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017.aspx)FSRH CEU statement: Drospirenone 4mg progestogen-only Pill (Slynd® ) (Jan 2024)[FSRH CEU Statement: Drospirenone Progestogen-only Pill (DRSP POP) (Jan 2024) | FSRH](https://www.fsrh.org/Public/Documents/fsrh-ceu-statement-drospirenone-progestogen-only-pill-drsp-pop.aspx?WebsiteKey=f858b086-d221-4a83-9688-824162920b1b)* Faculty of Sexual and Reproductive Healthcare (2023)

Response to new study on use of combined and progestogen-only hormonal contraception and breast cancer risk.[FSRH response to new study on use of CHC and POC and breast cancer risk (March 2023) | FSRH](https://www.fsrh.org/Public/Documents/response-to-study-on-use-of-chc-and-poc-and-breast-cancer.aspx) |

**Appendix A – example registered health professional authorisation sheet**

**PGD Name/Version Valid from: Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

**Registered health professional**

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

|  |
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| **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.** |
| **Name** | **Designation** | **Signature** | **Date** |
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**Authorising manager**

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| --- |
| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.** |
| **Name** | **Designation** | **Signature** | **Date** |
|  |  |  |  |

**Note to authorising manager**

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Add details on how this information is to be retained according to organisation PGD policy.